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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,459

Applicant(s)

WATANABE ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 10 recites the limitation "the surface active agent" in line two of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim is dependent upon 8 or 9, which do not mention a surface-active agent.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Makino *et al.* (EP 0 553 777). Claims 1, 2, 4 and 5 are drawn to a tablet containing a principle agent, a binder, a disintegrant, and saccharides with high wettability and moldability. The saccharides with high moldability are selected from the group consisting of lactose, maltitol, sorbitol and

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oligosaccharide. The saccharides with high wettability are selected from the group consisting of trehalose, mannitol, maltose, xylitol, erythritol and glucose.

Makino *et al.* teaches a compressed tablet that dissolvable in the oral cavity. The tablet of the invention comprises saccharides, binders and disintegrants. In example 1, the saccharides chosen are xylitol, and maltitol, along with disintegrants and binders. The tablets are compressed by means known in the art. These disclosures, along with others render the claims anticipated.

3. Claims 1, 2, 4, 5, 8, 9, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto *et al.* (EP 0 745 382). The claims are drawn to a compressed tablet comprising a principle agent, a binder, a disintegrants and saccharides. Claims 8, 9, 11 and 13 are drawn to a method of making the tablet of claims 1, 2, 4 and 5. The method comprises making a fluidized bed, spraying an aqueous solution and then drying it make granules, and finally compressing the granules.

Mizumoto *et al.* teaches a compressed tablet formulation comprising saccharides, binders and disintegrants. The tablet of the formulation uses two types of saccharides, high and low moldability. The saccharides of low moldability include lactose, mannitol, xylitol and the like. Saccharides of high moldability include maltose, maltitol, sorbitol and oligosaccharides (pg 5, lin. 20 – 29). The binding agents include powdered acacia gelatin and the like. The reference further discloses a method that comprises making a fluidized bed, spraying an aqueous solution, drying it to create granules and compressing it to make the tablets (pg 9, lin. 30 – 58). These disclosures, along with others, render the claims anticipated.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 –14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (EP 0 745 382) in view Sangekar *et al.* (USPN 3957662). As previously discussed the claims are drawn to a compressed tablet and a method of making it. The tablet comprises saccharides, disintegrants, binders and surface-active agents. The process comprises making a fluidized bed, spraying an aqueous solution, drying it to make granules and compressing the granules into tablets.

It have been previously discussed how Mizumoto discloses many of the essential elements of the claimed invention. The reference however differs from the claimed invention in that Mizumoto does not explicitly disclose the inclusion of surface-active agents, the reference merely suggests the inclusion of lubricants.

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It is known in the art of tablet production that surfactants, can be used as lubricants in order to improve disintegration and dissolution. As established in Sangekar *et al.*, tablets containing surfactants are more easily dispersed and have better disintegration (Abstract; col. 2, lin. 18 – 34).

Also with regard to claims 1 and 2, which recited limitations as to how the tablets are obtained, these limitations are a process of making, yet a product is claimed. These claims are considered to be product-by-process claims, therefore these limitations are not considered. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

With regard to claims 3, 12 and 14, which recite limitation as to the ratio of one type of saccharide to another, and concentration of the saccharides in the formulation, these limitation are not taken in to consideration. These recitations of optimal ranges can be determined through routine experimentation. The general combination of saccharides, binders, disintegrants, and surface-active agents is present in the prior art. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparations of various compressed tablet formulations having

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various amounts of the actives is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With this in mind one of ordinary skill in the art would have been motivated to follow the suggestions of Mizumoto and include the surfactants of Sangekar as lubricants in order to improve the disintegration and dissolution time of the compressed tablet formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions and knowledge in the art with an expected result of a compressed tablet with improved disintegration and dissolution time.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carr *et al.* (USPN 3878217) discloses a formulation that can be formed into compressed tablets comprising an active agent, saccharides, binders and disintegrants. Buehler *et al.* (USPN 4054658), Okada *et al.* (USPN 4211769), and Carr *et al.* (USPN 4180583 and 3965257) all disclose compressed tablet formulations comprising saccharides, surfactants, binders and disintegrants.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
August 12, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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